CONFIDENTIAL DOCUMENT

K080880

510(k) Summary (as required by 21 CFR 807.92(c))

APR - 9 2008

Manufacturer Name and Address
NEXT Mobility LLC
7444 Haggerty Road
Canton, MI 48187
Phone (734) 207-3405
Fax (734) 207-2642

Contact Person
Joseph Azary
Regulatory Consultant
543 Long Hill Avenue
Shelton, CT 06484
Phone (203) 944-9320
Fax (203) 944-9317

Prepared By:
Chris White
Joseph Azary

Date Prepared
Revised March 25, 2008

Name of Device
1) RTM
2) Oval

Classification Name
Wheelchair, Mechanical

Identification of Predicate Device
Sunrise Medical Model Quickie GT Manual Wheelchair (K850536)

Description of the Device
Intended Use
The RTm and Oval wheelchairs are intended to provide mobility to persons limited to a seated position that are capable of operating a manual wheelchair.

Comparison to Predicate Device
This device has a similar intended use and technological characteristics as the predicate device. The device and the predicate device are both mechanical wheelchairs. Comparisons demonstrate substantial equivalence.

Non-Clinical Tests Performed
All applicable tests were voluntarily conducted in accordance with the following standards:

ISO 7176-5 Determination of Overall Dimensions, Mass, and Turning Space

ISO 7176-15 Requirements for information disclosure, documentation, and labeling

ISO 7176-16 Resistance to ignition of upholstered parts requirements and test methods.

ISO 7176-1 Determination of Static Stability

ANSi/RESNA WC Volume 1-1998 Section 93 Maximum Overall Dimensions

Where applicable a 100 kg dummy (plus 12.4 kg) as specified in ISO 7176 – 11 was used.

Technological Characteristics
The device has been subjected to and successfully passed testing to voluntary standards.

Summary
We believe the subject devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2008

NEXT Mobility, LLC
c/o Underwriters Laboratories, Inc.
Mr. Jeff D. Rongero
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K080880
Trade/Device Name: RTm and Oval
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: March 27, 2008
Received: March 31, 2008

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: 1) RTm 2) Oval

Indications For Use:

The RTm and Oval wheelchairs are intended to provide mobility to persons limited to a seated position that are capable of operating a manual wheelchair.

Prescription Use _____ AND/OR Over-The-Counter Use __X_
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080880